Veterans Affairs pursuant to 38 U.S.C. 7401–7408.

(5) If the individual practitioner is working at a health care facility operated by the Department of Veterans Affairs on a contractual basis pursuant to 38 U.S.C. 8153 and, in the performance of his duties, prescribes controlled substances, confirm that the individual practitioner meets the criteria for eligibility for appointment under 38 U.S.C. 7401–7408 and is prescribing controlled substances under the registration of such facility.

(b) An institutional practitioner that elects to conduct identity proofing must provide authorization to issue the authentication credentials to a separate entity within the institutional practitioner or to an outside credential Service provider or certification authority that meets the requirements of §1311.105(a).

(c) When an institutional practitioner is conducting identity proofing and submitting information to a credential service provider or certification authority to authorize the issuance of authentication credentials, the institutional practitioner must meet any requirements that the credential service provider or certification authority imposes on entities that serve as trusted agents.

(d) An institutional practitioner that elects to conduct identity proofing and authorize the issuance of the authentication credential as provided in paragraphs (a) through (c) of this section must do so in a manner consistent with the institutional practitioner's general obligation to maintain effective controls against diversion. Failure to meet this obligation may result in remedial action consistent with §1301.36 of this chapter.

(e) An institutional practitioner that elects to conduct identity proofing must retain a record of the identity-proofing. An institutional practitioner that elects to issue the two-factor authentication credential must retain a record of the issuance of the credential.

§ 1311.115 Additional requirements for two-factor authentication.

(a) To sign a controlled substance prescription, the electronic prescription application must require the practitioner to authenticate to the application using an authentication protocol that uses two of the following three factors:

(1) Something only the practitioner knows, such as a password or response to a challenge question.

(2) Something the practitioner is, biometric data such as a fingerprint or iris scan.

(3) Something the practitioner has, a device (hard token) separate from the computer to which the practitioner is gaining access.

(b) If one factor is a hard token, it must be separate from the computer to which it is gaining access and must meet at least the criteria of FIPS 140–2 Security Level 1, as incorporated by reference in §1311.08, for cryptographic modules or one-time-password devices.

(c) If one factor is a biometric, the biometric subsystem must comply with the requirements of §1311.116.

§ 1311.116 Additional requirements for biometrics.

(a) If one of the factors used to authenticate to the electronic prescription application is a biometric as described in §1311.115, it must comply with the following requirements.

(b) The biometric subsystem must operate at a false match rate of 0.001 or lower.

(c) The biometric subsystem must use matching software that has demonstrated performance at the operating point corresponding with the false match rate described in paragraph (b) of this section, or a lower false match rate. Testing to demonstrate performance must be conducted by the National Institute of Standards and Technology or another DEA-approved government or nongovernment laboratory. Such testing must comply with the requirements of paragraph (h) of this section.

(d) The biometric subsystem must conform to Personal Identity Verification authentication biometric acquisition specifications, pursuant to NIST SP 800–76–1 as incorporated by reference in §1311.08, if they exist for the biometric modality of choice.

(e) The biometric subsystem must either be co-located with a computer or PDA that the practitioner uses to issue